

Surgical instruments — Metallic materials —

Part 1: Stainless steel

The European Standard EN ISO 7153-1:2000 has the status of a
British Standard

ICS 11.040.30; 77.140.20

Committees responsible for this British Standard

The preparation of this British Standard was entrusted by the Health Care Standards Policy Committee (HCC/-) to Technical Committee CH/43, upon which the following bodies were represented:

British Steel Industry
 British Surgical Trades Association
 Department of Health
 Institute of Sterile Services Management
 Medical Sterile Products Association
 National Association of Theatre Nurses
 Royal College of Nursing
 Royal College of Surgeons of Edinburgh
 Royal College of Surgeons of England

This British Standard, having been prepared under the direction of the Health Care Standards Policy Committee, was published under the authority of the Standards Board and comes into effect on 31 October 1991

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National foreword

This British Standard is the official English language version of EN ISO 7153-1:2000. It is identical with ISO 7153-1:1991.

The UK participation in its preparation was entrusted to Technical Committee CH/43, Surgical instruments, which has the responsibility to:

- aid enquirers to understand the text;
- present to the responsible international/European committee any enquiries on the interpretation, or proposals for change, and keep the UK interests informed;
- monitor related international and European developments and promulgate them in the UK.

A list of organizations represented on this committee can be obtained on request to its secretary.

Cross-references

Attention is drawn to the fact that CEN and CENELEC Standards normally include an annex which lists normative references to international publications with their corresponding European publications. The British Standards which implement these international or European publications may be found in the BSI Standards Catalogue under the section entitled “International Standards Correspondence Index”, or by using the “Find” facility of the BSI Standards Electronic Catalogue.

A British Standard does not purport to include all the necessary provisions of a contract. Users of British Standards are responsible for their correct application.

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Summary of pages

This document comprises a front cover, an inside front cover, pages i and ii, the EN ISO title page, pages 2 to 6, an inside back cover and a back cover.

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English version

Surgical instruments — Metallic Materials — Part 1: Stainless steel

(ISO 7153-1:1991, including Amendment 1:1999)

Instruments chirurgicaux — Matériaux
métalliques — Partie 1: Acier inoxydable
(ISO 7153-1:1991, Amendment 1:1999 inclus)

Chirurgische Instrument — Metallische
Werkstoffe — Teil 1: Nichtrostender Stahl
(ISO 7153-1:1991, einschließlich Änderung 1:1999)

This European Standard was approved by CEN on 9 September 2000.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Management Centre has the same status as the official version.

CEN members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

CEN

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

Central Secretariat: rue de Stassart 36, B-1050 Brussels

Foreword

The text of the International Standard from Technical Committee ISO/TC 170, Surgical instruments, of the International Organization for Standardization (ISO) has been taken over as an European Standard by Technical Committee CEN/TC 55, Dentistry, the Secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by April 2001, and conflicting national standards shall be withdrawn at the latest by April 2001.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

1 Scope

This part of ISO 7153 contains a survey and a selection of stainless steels available for use in the manufacture of surgical, dental and specific instruments for orthopaedic surgery.

NOTE 1 When selecting the grade of steel and the shape, dimensions and delivery conditions of the raw material for manufacturing surgical instruments, it is necessary to take into account factors, such as the design of the instrument or the production facilities of the manufacturer, that are not covered by this part of ISO 7153. For this reason, it is not intended, nor is it possible, that the information given in this part of ISO 7153 should remove the decision-making responsibility from the instrument manufacturer for selecting an appropriate raw product with suitable properties; nor is it intended to preclude the use of other types of steel in the manufacture of instruments, such as the use of carbon steel for cutting instruments. International Standards for surgical instruments, when published, should be observed when making this decision as they may contain additional or new information to be taken into account when selecting appropriate steel grades.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this part of ISO 7153. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this part of ISO 7153 are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 683-13:1986, Heat-treatable steels, alloy steels and free-cutting steels — Part 13: Wrought stainless steels.

ISO 4957:1980, Tool steels